No. 24-1019

IN THE
UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Plaintiff-Appellee,

vs.

KEITH M. ELLISON, in his official capacity as Attorney General of the State of Minnesota,

Defendant-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA

APPELLANT'S BRIEF

GOODWIN PROCTER LLP
William M. Jay
Benjamin Hayes
Collin M. Grier
1900 N Street, N.W.
Washington, DC 20036
Telephone: (202) 346-4000
wjay@goodwinlaw.com
bhayes@goodwinlaw.com
cgrier@goodwinlaw.com
ATTORNEYS FOR PLAINTIFF-APPELLEE
(continued on inside cover)

KEITH ELLISON
Attorney General
State of Minnesota
Nick Pladson
Jason Pleggenkuhle
Noah Lewellen
Assistant Attorneys General
445 Minnesota St., Suite 1400
St. Paul, MN 55101-2128
Telephone: (651) 300-7083
ATTORNEYS FOR DEFENDANT-APPELLANT
(continued on inside cover)

FELHABER LARSON
David L. Hashmall
200 South 6th Street, Suite 2200
Minneapolis, MN 55402
Telephone: (612) 339-6321
Facsimile: (612) 338-0535
dhashmall@felhaber.com

ATTORNEYS FOR PLAINTIFF-APPELLEE

Nick.Pladson@ag.state.mn.us
Jason.Pleggenkuhle@ag.state.mn.us
Noah.Lewellen@ag.state.mn.us

ATTORNEYS FOR DEFENDANT-APPELLANT

SUMMARY OF CASE AND REQUEST FOR ORAL ARGUMENT

The district court preliminarily enjoined Minnesota from enforcing its law barring generic drug manufacturers from excessively increasing prices. The Act applies equally to all drug manufacturers, whether in- or out-of-state, but the injunction applies only to out-of-state manufacturers who choose to sell their drugs to an out-of-state intermediary before they are sold, distributed, or dispensed in Minnesota. *See* Minn. Stat. §§ 62J.841-846 ("The Act"). The district court's injunction creates a loophole for out-of-state manufacturers to side-step the Act's prohibitions, undermining the Minnesota Legislature's sovereign power to protect health and safety by ensuring access to life-sustaining and life-saving medications.

The district court erred. The dormant Commerce Clause does not bar Minnesota from directly regulating out-of-state drug manufacturers when (1) they hold Minnesota licenses permitting their drugs to be sold in Minnesota, (2) the drugs they manufacture for sale in Minnesota are excessively priced, and (3) their excessively priced drugs are actually sold, dispensed, or delivered in Minnesota. Here, the Act is constitutional because it will only ever apply to out-of-state transactions with substantial connections in Minnesota.

Oral argument is appropriate because of the unique and important issues presented and, if granted, the Attorney General requests oral argument be held in St. Paul, Minnesota and be 20 minutes per side.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

Federal Cases

State Cases

Federal Statutes

State Statutes

Federal Rules

State Regulations

Other Authorities

JURISDICTIONAL STATEMENT

The District Court had jurisdiction over Appellees' federal constitutional claims under 28 U.S.C. § 1331. This Court has jurisdiction under 28 U.S.C. § 1292(a)(1) to review the District Court's December 4, 2023 order granting Appellees motion for a preliminary injunction.[1] The District Court entered judgment on December 4, 2023.[2] Appellant timely filed a Notice of Appeal on January 2, 2023.[3]

[1] Appellant's Addendum ("Add."), 1-25; R. Doc. 42, at 1-25.
[2] Add. 26-27; R. Doc. 43, at 1-2.
[3] Joint Appendix ("App."), 645-46; R. Doc. 47, at 1-2.

STATEMENT OF ISSUES

1. Minnesota's ban on generic drug price-gouging applies with equal force to in- and out-of-state drug manufacturers licensed by Minnesota's Board of Pharmacy. There is no question that Minnesota can regulate the price of drugs that Minnesota-licensed out-of-state manufacturers send directly into the state. Does the dormant Commerce Clause sever Minnesota's sovereign power to regulate the price of the same Minnesota-bound drugs when the same Minnesota-licensed out-of-state manufacturer sends its drugs into Minnesota indirectly, through a Minnesota-licensed out-of-state distributor?

   Apposite Authorities:

   Nat'l Pork Producers Council v. Ross, 593 U.S. 356 (2023)
   CTS Corp. v. Dynamics Corp. of Am., 481 U.S. 69 (1987)
   Exxon Corp. v. Gov. of Maryland, 437 U.S. 117 (1978)

STATEMENT OF THE CASE

In 2023, the Minnesota legislature acted to limit the amount that prescription drug manufacturers could hike the price of generic drugs over the prior year on drugs sold in Minnesota. The Act applies uniformly to all Minnesota-licensed drug manufacturers, including (1) all in-state manufacturers, (2) all out-of-state manufacturers that sell their generic drug products *directly* into Minnesota, and (3) all out-of-state manufacturers that *indirectly* sell their generic drugs—through out-of-state intermediaries—into Minnesota. The district court's injunction only exempts the third category of manufacturers from the Act's requirements.

I. MINNESOTA'S LONGSTANDING PRESCRIPTION DRUG LICENSING REGIME ONLY REGULATES SUPPLY CHAIN PARTICIPANTS THAT VOLUNTARILY SEEK ACCESS TO MINNESOTA'S MARKETPLACE.

The Minnesota Board of Pharmacy's (the "Board") regulates the manufacture, distribution, sale, and administration of prescription drugs in Minnesota. The Board has licensed and regulated manufacturers, including out-of-state manufacturers, for over 60 years.[4] Likewise, the Board has regulated forms of unfair drug pricing for over 50 years.[5] In 2023, Minnesota augmented these regulations, passing the Act to

[4] Act of April 14, 1961, Reg. Session, ch. 394 §§ 1, 7, 1961 Minn. Laws 602-3; Minn. Stat. § 151.252, subd. 1; Add. 29-32.
[5] Minn. Stat. § 151.061 (1973).

forbid drug manufacturers from imposing excessive price increases on generic prescription drugs sold, distributed, or dispensed in Minnesota.[6]

Even in the absence of federal regulation, Minnesota's pharmaceutical drug marketplace is not unregulated. One cannot compound drugs in a Wisconsin basement, provide them to distributors in Iowa, and expect to make them legally available for purchase in Minnesotan. Rather, when a pharmacy wants to dispense drugs in Minnesota, it must be licensed by the Board.[7] If a wholesaler wants to distribute drugs to pharmacies in Minnesota, it must be licensed in Minnesota.[8] And if a manufacturer wants its drugs to be eligible for purchase in the state, it, too, must obtain a license from the Board. The Board also licenses and regulates third-party logistics providers that deliver drugs into Minnesota,[9] outsourcing facilities,[10] pharmacies,[11] pharmacists,[12] and medical professionals[13] who prescribe and administer prescription drugs to consumers in Minnesota.[14] Accordingly, as explained *infra*, prescription drugs may legally be sold, distributed, or dispensed in

---

[6] Add. 29-32.
[7] Minn. Stat. § 151.19, subd. 1(a).
[8] Minn. Stat. § 151.47.
[9] Minn. Stat. § 151.471 (licensing requirements for third-party logistics providers).
[10] Minn. Stat. § 151.252, subd. 1a.
[11] Minn. Stat. § 151.19, subd. 1(a).
[12] Minn. Stat. § 151.34(13).
[13] Minn. Stat. § 151.19, subd. 4.
[14] Minn. Stat. § 151.37 (licensing medical professionals who prescribe, dispense, or administer drugs).

Minnesota only if both the manufacturer and the party bringing the drug into the state voluntarily sought and obtained a Minnesota license to do so from the Board.[15]

Minnesota's prescription drug regulations are a quintessential expression of a state's police power to protect its consumers' health and safety, track and recover defective product, quickly correct violations, and ensure access to life-saving and life-sustaining medications.[16] Through the Board, Minnesota controls which drugs enter the Minnesota marketplace by, for example, embargoing adulterated drugs that have entered state borders,[17] regulating wholesalers engaged in the physical act of bringing drugs into the state,[18] and requiring in-state and out-of-state manufacturers to submit to inspections of their manufacturing facilities.[19]

The Board's regulations necessarily have extraterritorial effects, as the majority of drug manufacturers in the United States are not headquartered in Minnesota. However, these manufacturers choose to make their drugs available for purchase in the state, and voluntarily agree to follow Minnesota laws to do so. The Board's licensing scheme allows Minnesota to regulate these out-of-state companies to the extent that they supply drugs, directly or indirectly, to consumers in Minnesota.

---

[15] Minn. Stat. §§ 151.46 & 151.252(g).
[16] *See generally* Minn. Stat. § 151.06 (describing powers and duties).
[17] Minn. Stat. § 151.38.
[18] Minn. Stat. § 151.147.
[19] Minn. Stat. § 151.252(g).

II. PRESCRIPTION DRUG MANUFACTURERS CONTROL DOWNSTREAM PRICING AND DRUG ACCESSIBILITY IN MINNESOTA.

Prescription drug manufacturers are the start of the drug-supply chain and have the most influence over the pharmaceutical prices ultimately paid by consumers.[20] Manufacturers set drug prices by promulgating a list price for their products, known as the "wholesale acquisition cost," or "WAC."[21] Various trade publications and advertisements provide WAC[22] prices to the general public nationally and in Minnesota.[23] Pharmacies, either directly or through contracts negotiated by group purchasers, typically purchase manufacturers' drugs from wholesalers based on a percentage of the WAC.[24] The retail cost to uninsured or underinsured end-payers is built off the manufacturer-set WAC.[25]

Before manufacturers can make their drugs available for purchase in Minnesota, they must first apply for and obtain a license from the Board.[26] Drug manufacturers must obtain Minnesota licenses for each facility—whether in- or out-

---

[20] App. 13; R. Doc. 1, at 11. App. 124-25; R. Doc. 26-2, at 19-20.
[21] *Id.*
[22] AWP, or "average wholesale price," may also be advertised. AWP is by convention approximately 1.2 times WAC. App. 96; R. Doc. 26-1, at 40.
[23] App. 96-97; R. Doc. 26-1, at 40-41.
[24] App. 78-79, 96; R. Doc. 26-1, at 22-23, 40.
[25] App. 362; R. Doc. 26-6, at 22. App. 545; R. Doc. 28, at 2.
[26] *See* Minn. Stat. § 151.252, subds. 1(a) and 2; *see also,* Minn. Stat. §§ 151.35(1) (defining "adulterated drugs" to include those manufactured at an unlicensed facility) *and* 151.34(1) (prohibiting the manufacture, sale, delivery, or holding of adulterated drugs).

of-state—wherever they manufacture drugs to be sold in Minnesota.[27] This is true even if a drug manufacturer never sells drugs directly into the state, but opts to use out-of-state intermediaries to distribute its drugs into Minnesota.[28] By obtaining a license and completing their annual license renewal, all manufacturers agree to "operate in a manner prescribed by federal and state law and according to Minnesota Rules."[29] As of July 2023, the Board licensed 973 drug manufacturing facilities; 86 licensed facilities are located in Minnesota, and 887 licensed facilities are facilities are located in other states.[30] Like the Act, Board regulations apply equally to both categories of manufacturers.

Although some manufacturers sell drugs directly to consumers in Minnesota, most out-of-state manufacturers sell their drugs to wholesale distributors that re-sell these drugs in Minnesota.[31] Minnesota wholesale drug distributor licensing requirements are similar to those for drug manufacturers. Wholesale drug distributors also must apply to the Board, obtain a separate license for each distribution facility, whether in- or out-of-state, and must renew their license

[27] Minn. Stat. § 151.252; Minn. R. 6800.1400, subp. 3.
[28] *Id*.
[29] Minn. Stat. § 151.252, subd. 1(d).
[30] App. 484; R. Doc. 27, at 3.
[31] *See, e.g.*, App. 48; R. Doc. 20, at 2. App. 656; R. Doc. 19, at 2.

annually.[32] Wholesale distributors also agree, and reaffirm annually, to operate in a manner prescribed by federal and Minnesota law.[33]

In Minnesota, wholesale drug distributors purchase drugs solely for the purpose of resale, but cannot sell directly to patients or consumers.[34] As of July 2023, Minnesota's Board licensed 717 drug wholesale distribution facilities; 82 licensed facilities are located in Minnesota, and 635 licensed facilities are located outside of the state.[35] The "three largest wholesale distributors who control over 90% of the market" are all licensed by Minnesota's Board, and their facilities make up some of those 82 in-state facilities.[36]

In Minnesota, manufacturers can hold both a manufacturers license and wholesale distributor license—indeed, at least one of AAM's members has done so[37]—and manufacturers are free to engage in direct sales to Minnesota pharmacies upon obtaining such licensure. That certain manufacturers choose not to ship directly to Minnesota pharmacies, but instead operate through a circuitous path of wholesale distributors across multiple states, is an operational and business decision they

[32] Minn. Stat. § 151.147, subd. 1a.
[33] Minn. Stat. § 151.147, subd. 1a(d).
[34] Minn. Stat. § 151.146. & 151.19, subd. 1; *see also* Minn. Stat. § 151.441, subds. 2, 13(4).
[35] App. 487; R. Doc. 27, at 6.
[36] App. 14; R. Doc. 1, at 12. App. 489-501; R. Doc. 27-1, at 1-13.
[37] App. 484-488; R. Doc. 27, at 3-7.

chose. By making that choice, drug manufacturers must be prepared to conform their interstate conduct to more than one set of laws, including Minnesota's Act.

III. THE GENERIC DRUG MARKET IS BROKEN AND ENABLES MANUFACTURER PRICE-GOUGING THAT HARMS CONSUMERS IN MINNESOTA.

Generic drugmakers routinely exploit monopolies or near-monopolies in the marketplace to engage in exorbitant price hikes.[38] Indeed, Teva and Sandoz, two of AAM's members, recently paid hundreds of millions of dollars in criminal fines to the US Department of Justice for admittedly running a domestic antitrust cartel.[39] Prior to that, the US Department of Health and Human Services singled out Teva for manipulating the consolidation of generic drug-making to artificially restrict supply to manufacture a rationale, or pretext, to make unconscionable price spikes.[40]

These price spikes are absurd. For example, the manufacturer of Tetracycline, a generic antibiotic that is widely-prescribed for a diverse array of bacterial infections, imposed a 17,700% price increase recently.[41] The price for Doxycycline, another generic antibiotic, was hiked over 1,900% in a single year.[42] These increases were unrelated to any increase in production cost but presented an enticing

---

[38] App. 147-151; R. Doc. 26-3, at 10-14.
[39] Dan Haar, *The huge pharma settlement in CT that's quietly making history*, CT Insider (Dec. 15, 2022), *available at* https://perma.cc/ZB8Q-URHW; Marcy Gordon, *Drugmaker Sandoz Inc. to pay $195 million fine in antitrust case*, PBS (Mar. 2, 2020), *available at* https://perma.cc/Z27G-ELWE.
[40] App. 149; R. Doc. 26-3, at 12.
[41] App. 150; R. Doc. 26-3, at 13.
[42] *Id.*

opportunity to raise prices due to a decrease in supply or competition, and are ultimately borne by the consumer.[43] Generic drug manufacturers have been singled out for this conduct.[44]

Between 2010 and 2015, 48 generic drugs experienced an over-500% price increase in a single year.[45] Report after report has found that excessive price increases are untethered to market pressures, but rather constitute "price gouging" tied to selective acquisitions to monopolize inelastic consumer markets and other anticompetitive behavior.[46] While it is the minority of generic drugs that experience extreme price increases, these price increases are unconscionable and risk the health and safety of Minnesotans who rely on these drugs.[47]

Most recently, in 2023 a Minnesota Department of Health report ("MDH Report") found at least nine examples of price increases exceeding 50% in a single year, and 127 examples meeting lower criteria.[48] The MDH Report, as with the Government Accountability Office's ("GAO") study,[49] found that a minority of manufacturers engaged in extraordinary price increases.[50]

---

[43] *Id.*
[44] App. 149; R. Doc. 26-3, at 12.
[45] App. 169-77; R. Doc. 26-4, at 17-26.
[46] App. 254-94; R. Doc. 26-5, at 45-85.
[47] App. 169-77; R. Doc. 26-4, at 17-26.
[48] App. 456-58; R. Doc. 26-7, at 22-24.
[49] App. 153-209; R. Doc. 26-4, at 1-57.
[50] App. 452-61; R. Doc. 26-7, at 18-27.

Pharmacies in Minnesota use manufacturers' published WAC prices to price generic drugs for sale in Minnesota.[51] When manufacturers engage in price-gouging they directly impact prices ultimately charged to consumers in Minnesota, and are especially harmful for Minnesotans who are uninsured, underinsured, on a fixed income, or pay out-of-pocket.[52] As a result, many consumers in Minnesota must choose between paying for basic needs or paying for medications.[53] "[A]n estimated 9% of Minnesotans—or more than half a million people—had not filled a prescription due to cost in the preceding 12 months according to a 2017 survey.[54] After receiving MDH's 2023 report, the Minnesota Legislature passed the Act.

IV. MINNESOTA BANS PRICE-GOUGING BY GENERIC DRUG MANUFACTURERS.

Minnesota adopted the Act to protect consumers in Minnesota from excessive price increases that prevent them from accessing critical, life-saving generic drugs. The Act seeks to protect in-state consumers from wild price hikes on generic drugs in Minnesota. The Act does not seek to force manufacturers to lower prices, but to moderate price changes, providing consumers access to predictably-priced medications.

[51] App. 545; R. Doc. 28, at 2.
[52] App. 371-75; R. Doc. 26-6, at 31-35.
[53] App. 358-59; R. Doc. 26-6, at 18-19.
[54] Id.

The Act forbids industry practices that the broken generic pharmaceutical market has proven unable to correct. The Act bars generic drug manufacturers from "impos[ing], or caus[ing] to be imposed, an excessive price increase, whether directly or through a wholesale distributor, pharmacy, or similar intermediary, on the sale of any generic or off-patent drug *sold, dispensed,*[55] *or delivered to any consumer in the state.*"[56]

Under the Act, an "excessive price increase" occurs when:

> (1) the price increase, adjusted for inflation utilizing the Consumer Price Index, exceeds:
>
> (i) 15 percent of the wholesale acquisition cost over the immediately preceding calendar year; or
>
> (ii) 40 percent of the wholesale acquisition cost over the immediately preceding three calendar years; and
>
> (2) the price increase, adjusted for inflation utilizing the Consumer Price Index, exceeds $30 for:
>
> (i) a 30-day supply of the drug; or
>
> (ii) a course of treatment lasting less than 30 days.[57]

---

[55] A "dispenser" is a "retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control" and can only be done by those authorized by law to dispense or administer prescription drugs. Minn. Stat. § 151.441, subd. 2.

[56] Add. 29 (emphasis added). Minn. Stat. § 62J.842, subd. 1 (emphasis added). The Act does not apply to wholesale distributors or pharmacies. Add. 30, at subd. 3.

[57] Add. 29-30. Minn. Stat. § 62J.842, subd. 2.

The Act does not apply to the initial price a drug manufacturer sets when a drug first enters the Minnesota market. It only regulates the speed with which a drug manufacturer increases the price in the years that follow. Thus, it is designed to protect consumers who have established a need for a drug based on its initial price—and may be dependent on it to survive. The Act targets drug manufacturers because they are the entities most responsible for establishing the generic drug prices ultimately borne by consumers. As explained *supra*, manufacturers set initial drug prices and subsequent intermediaries pass these costs through to consumers; they are the root of the problem.

The Act works like this: if the list price for a generic drug was $100 for a 30-day supply one year, and its list price increased to $115 in the next year, the price increased by 15%, but not $30, so there is no violation of the Act. Rather, the Act targets truly excessive price increases. For example, if a drug's WAC price increased from $7.16 to $139.89 in a single year, the Act would be triggered because the list price increased by over 1,800% *and* by over $30 for a 30-day prescription. Such price hikes are not standard within the generic drug industry: both the Minnesota Department of Health and the GAO have found that only a minority of manufacturers have engaged in extraordinary price hikes at levels prohibited by the Act.[58] The Act targets the industry's worst actors.

[58] App. 154; R. Doc. 26-4, at 2. App. 455-61; R. Doc. 26-7, at 21-27.

When the Commissioner of the Minnesota Department of Health is notified that a manufacturer hiked the price of a drug sold, dispensed, or distributed in Minnesota beyond the Act's thresholds, the Commissioner must notify the manufacturer that the price increase potentially violates the Act. Other agencies are similarly empowered to do so.[59] Upon receipt of this notice, the manufacturer must provide drug cost information to the Attorney General, including information about external circumstances that might explain the price hike.[60] The Attorney General may exercise his prosecutorial discretion to petition a court for remedial actions, including repayment to Minnesota consumers harmed by any in-state sales, distribution, or dispensing of drugs that violate the Act.[61] After receiving notice and an opportunity to participate in the Attorney General's investigation, manufacturers are provided additional due process to challenge an enforcement action.[62]

V. THE DISTRICT COURT'S ORDER OVERRIDES MINNESOTA'S POLICE POWERS TO CARVE A PRICE-GOUGING LOOPHOLE IN THE ACT.

Appellee, the Association for Accessible Medicines ("AAM"), commenced this litigation in July 2023, days after the Act was enacted, challenging the Act's constitutionality under the dormant Commerce Clause, the Due Process Clause, the

[59] Minn. Stat. § 62J.844, subd. 1. No warnings have yet been sent.
[60] *Id.*, subd. 2.
[61] *Id.*, subd. 3.
[62] *Id.*

Horizontal Separation of Powers, and Sections 1983 and 1988.[63] AAM sued Appellant, the Minnesota Attorney General ("Attorney General"), in his official capacity because the Minnesota Legislature assigned the Attorney General responsibility for enforcing the Act.[64]

On July 20, 2023, AAM moved to enjoin the Act only as it applied to the third group of regulated drug manufacturers: AAM's "members, or any of their agents, privies, and licensees, *based on any member's sale of generic drugs or off-patent drugs or biosimilars that occurs outside of Minnesota*."[65] AAM did not claim that Minnesota's Act discriminates against out-of-state entities.[66] AAM claimed the Act violates the dormant Commerce Clause's bar on state laws that "directly" regulate "commerce wholly outside the State."[67]

On December 4, 2023, the district court granted AAM's motion for a preliminary injunction, in part.[68] While the Minnesota Legislature wrote the Act to apply to all drug manufacturers—in- or out-of-state—the district court carved out,

---

[63] App. 3-33; R. Doc. 1, at 1-31
[64] *Id.*
[65] R. Doc. 22, at 2.
[66] App. 603-04; R. Doc. 39, at 55-56.
[67] App. 5; R. Doc. 1, at 3.
[68] The preliminary injunction was granted "[i]n part," because the district court limited it to enforcement of sections 62J.841-62J.842 and 62J.844-62J.845, and only "based on any [AAM] member's sale of generic or off-patent drugs outside of Minnesota." Add. 24-25; R. Doc. 42, at 24-25. AAM sought to enjoin additional aspects of the Act, including sections 62J.843 and 62J.846, which the district court declined to enjoin. *Compare* R. Doc. 22, at 2 *with* Add. 24-25; R. Doc. 42, at 24-25.

under the auspices of the dormant Commerce Clause, just a subset of regulated entities: out-of-state manufacturers that choose to pass their drugs through one or more out-of-state intermediaries before being sold, distributed, or dispensed to consumers in Minnesota. The Attorney General appeals.

SUMMARY OF ARGUMENT

Drug manufacturers voluntarily obtain Minnesota licenses for the privilege of making their drugs available in Minnesota. In so doing, manufacturers agree to abide by Minnesota law and operate within its pharmaceutical regulatory scheme, including the Act's price-gouging prohibition. Nonetheless, the district court erroneously found that manufacturers' voluntary and affirmative acts to reach into Minnesota are insufficient to justify Minnesota's price-gouging regulation.[69]

When a manufacturer imposes an excessive price increase on a drug, the costs are passed through the entire supply chain where vulnerable consumers in captive markets bear the ultimate downstream costs. Because of the nature of the prescription drug distribution market, limiting states' regulatory power to just the final or penultimate in-state transaction effectively prevents states from regulating the party most culpable for excessive price increases – prescription drug manufacturers.

[69] Add. 10-11; R. Doc. 42, at 10-11.

The district court found the Act likely violates the dormant Commerce Clause's bar on direct regulation of out-of-state commerce, but only when applied to out-of-state manufacturers who send drugs into Minnesota indirectly, through out-of-state intermediaries. The district court erred as a matter of law, and this Court should vacate the preliminary injunction, because the Act only prescribes conditions for drugs sold, distributed, or dispensed to consumers in Minnesota and manufactured by entities with a substantial nexus in the state. Like numerous laws in every state in the country, the Act simply requires manufacturers to take steps to make Minnesota-bound drugs Minnesota-compliant. Unless vacated by this Court, the district court's preliminary injunction will provide a clear roadmap for any out-of-state manufacturer to side-step the Act (or any other in-state, police power regulation) by choosing to distribute their products through an out-of-state intermediary before they enter Minnesota.

ARGUMENT

I. DEMOCRATICALLY-ENACTED STATE LAWS RECEIVE A DEFERENTIAL STANDARD OF REVIEW THE DISTRICT COURT FAILED TO PROVIDE.

This Court reviews the grant of a preliminary injunction for abuse of discretion, examining factual findings for clear error and legal conclusions *de novo*. *Eggers v. Evnen*, 48 F.4th 561, 564 (8th Cir. 2022). Because there are no facts in dispute, this Court's review is *de novo*. When a preliminary injunction is based on an error of law, as it is here, it constitutes an abuse of discretion, and the injunction

should be vacated. *Minn. Citizens Concerned for Life, Inc. v. Swanson*, 692 F.3d 864, 872 (8th Cir. 2012).

Before preliminarily enjoining a state law, district courts "must ... make a threshold finding that a party is likely to prevail on the merits." *Planned Parenthood Minn., N. D., S.D. v. Rounds*, 530 F.3d 724, 732-33 (8th Cir. 2008). Because they are the product of "presumptively reasoned democratic processes," a "more rigorous standard" applies so that state laws are only thwarted "after an appropriately deferential analysis." *Id*. at 732-33 & n.6.

The district court's decision granting the preliminary injunction rests primarily on the conclusion that AAM "has established that it highly likely to succeed on the merits, and likelihood of success on the merits is '[t]he most important of the *Dataphase* factors.'"[70] As explained *infra*, review of this factor alone warrants reversal of the district court's preliminary injunction order. The district court erred as a matter of law and this Court should vacate the preliminary injunction and remand this case for discovery on the remaining claims.[71]

---

[70] Add. 20; R. Doc. 42, at 20 (citations omitted).

[71] The district court granted the Attorney General's motion to dismiss counts three and five of AAM's complaint. Add. 24-25; R. Doc. 42, at 24-25. Upon remand, the case will address AAM's three remaining counts: (1) whether the Act violates the dormant Commerce Clause's prohibition on direct regulation of commerce wholly outside a state; (2) whether the Act violates the Due Process Clause; and (3) whether the Act violates the dormant Commerce Clause under the *Pike*-balancing test.

II. THE DORMANT COMMERCE CLAUSE'S PRIMARY CONCERN IS DISCRIMINATORY STATE LAWS FAVORING IN-STATE BUSINESS.

The Commerce Clause vests Congress with the power to "regulate Commerce . . . among the several States." Art. I, § 8, cl. 3. Congress could use this power to regulate generic drug pricing, but it has not done so.[72] Even where Congress has not acted, however, "the negative or dormant implication of the Commerce Clause prohibits state taxation or regulation that discriminates against or unduly burdens interstate commerce and thereby impedes free private trade in the national marketplace." *General Motors Corp. v. Tracy*, 519 U.S. 278, 287 (1997) (cleaned up).

The "very core" of the Supreme Court's dormant Commerce Clause jurisprudence forbids "the enforcement of state laws 'driven by . . . economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors.'" *Nat'l Pork Producers Council v. Ross*, 593 U.S. 356, 368 (2023) (citation omitted)." State laws must instead "regulate[] even-handedly to effectuate a legitimate local public interest." *Id*. at 391 (citing *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)) (Sotomayor, J. and

[72] In contrast, Congress's choice to regulate *patented* prescription drugs preempts similar state pricing legislation. *See Biotechnology Indus. Org. v. Dist. of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007) (holding that federal patent law preempted state law regulating prices of patented drugs). Congress could preempt state regulation of generic prescription drugs, but has not done so.

Kagan, J., concurring) (noting that the *Pike* test is designed to detect discrimination). If a law does so, it generally "will be upheld unless the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits." *Id*. at 142.

The Court invokes a practical presumption against dormant Commerce Clause challenges where a state law does not discriminate: When a state law discriminates by seeking to "advantage in-state firms or disadvantage out-of-state rivals," the dormant Commerce Clause's silent prohibition is at its zenith, but when a party fails to allege discrimination, their dormant Commerce Clause challenge "begin in a tough spot." *Id*. Here, AAM has never alleged that the Act discriminates in any cognizable way.[73]

Accordingly, "absent discrimination, a state may exclude from its territory, or prohibit the sale therein of any articles which, in its judgment, fairly exercised, are prejudicial to the interests of its citizens." *Id*. at 369 (citation and quotations omitted). Indeed, since the founding, states have enacted an "immense mass" of "[i]nspection laws, quarantine laws, [and] health laws of every description" that have a "considerable influence on commerce outside their borders." *Id*. at 375. Nor is there anything unique or sacrosanct about price regulations under the dormant Commerce Clause. Indeed, "innumerable valid state laws affect pricing decisions in

[73] App. 3-33; R. Doc. 1, at 1-31. App. 603-05; R. Doc. 39, at 55-56.

other states—even so rudimentary a law as a maximum price regulation." *Healy v. Beer Inst., Inc*., 491 U.S. 324, 345 (1989) (Scalia, J., concurring).

Following the Court's decision in *Ross*, extraterritorial effects alone—even those impacting pricing—do not constitute violations of the dormant Commerce Clause. *Ross*, 598 U.S. 356 at 376.[74] The Court noted, however, that the dormant Commerce Clause still prohibits state regulation of commerce taking place "wholly outside" the state involving individuals "having no connection with [the regulating state]." *Ross*, 598 U.S. at 376, n.1 (citing *Edgar v. MITE Corp.*, 457 U.S. 624, 642–43 (1982) (plurality opinion)). The *Edgar* plurality's core concern was whether allowing a law to apply to wholly extraterritorial conduct would permit one state to "exalt [its] public policy . . . over that of another." *Id.* at 914 (internal citations omitted).[75]

---

[74] The Court noted some exceptions irrelevant to the matter at hand, like extraterritorial effects on instrumentalities of interstate commerce, like railroads. *Ross*, 598 U.S. at 380, n.2.

[75] The *Ross* majority cautioned, however, that the constitutional problem with the state law in *Edgar* was less that it "posed a dormant Commerce Clause question as much as one testing the territorial limits of state authority under the Constitution's horizontal separation of powers." *Id*. The Court rejected the notion that the dormant Commerce Clause provided the answer whenever there is "*any* question about the ability of a State to project its power extraterritorially." *Id*. (emphasis in original). Rather, "the antidiscrimination principle found in our dormant Commerce Clause" is just one of several enumerated Constitutional provisions it uses "to mediate competing claims of sovereign authority under our horizontal separation of powers." *Id*. at 376. But it is not an all-purpose tool with which to assess the constitutionality of every extraterritorial State law. *See* Donald H. Regan, *Siamese Essays: (I) CTS*
(Footnote Continued on Next Page.)

Here, the district court believed the Act ran afoul of *Edgar* not because it exalted Minnesota policy over another state's, but because it was a direct regulation of out-of-state transactions wholly outside Minnesota. The district court misapplied *Edgar's* second clause when it held that these transactions were "wholly outside" Minnesota, ignoring the deep regulatory tie each manufacturer chooses to have in Minnesota and dismissed the in-state conduct required to trigger the Act. Indeed, because the Act is only ever triggered by these significant in-state connections, and cannot be violated by wholly out-of-state transactions, the Act does not exalt Minnesota's public policy over any other state.

III. THE DISTRICT COURT ERRED IN FINDING THE ACT LIKELY VIOLATES THE DORMANT COMMERCE CLAUSE BECAUSE IT DOES NOT DIRECTLY REGULATE COMMERCE WHOLLY OUTSIDE MINNESOTA.

The Act applies to all Minnesota-licensed generic drug manufacturers and is only triggered when they excessively increase the price of their generic drugs that are actually sold, dispensed, or delivered to consumers in Minnesota. The Act is non-discriminatory, and thus presumptively constitutional. The district court misapplied the dormant Commerce Clause's so-called extraterritorial regulation doctrine that

---

Corp. v. Dynamics Corp. of America and Dormant Commerce Clause Doctrine; (II) Extraterritorial State Legislation, 85 MICH. L. REV. 1865, 1885 (1987) ("The extraterritoriality principle is not to be located in any particular clause" but rather is "one of those foundational principles of our federalism which we infer from the structure of the Constitution as a whole.").

stems primarily from *Edgar*. But *Edgar* and its progeny involve regulations inapposite and distinguishable from the Act. Moreover, each of the cases relied on by the district court struck down regulations because of overbreadth problems; they all could be applied to commerce with no connection to the regulating state at all.

Here, because regulated manufacturers are licensed in Minnesota, set prices that dictate the prices paid for drugs they supply to Minnesota's market, and the Act is only triggered by the in-state sale, distribution, or dispensing of a drug, the Act is not prohibited by the dormant Commerce Clause.

A. Edgar's Driving Principles Do Not Apply Here.

In *Edgar*, a plurality of the Court struck down an Illinois law that regulated out-of-state tender offers between a non-Illinois company and non-Illinois residents. 457 U.S. at 642. The purpose of the state law in *Edgar* was to protect Illinois shareholders of Illinois corporations facing hostile takeover bids. *Id*. at 626-30. Constitution problems arose with the law when, in some applications, it gave Illinois power to determine whether a tender offer in another state could proceed at all, even though no party to the transaction—neither the offering company *nor* any shareholder to whom the tender offer was to be delivered—had any connection to Illinois whatsoever. *Id.* at 641-42. Problematically, the Illinois law gave *Illinois* power to determine whether to allow a tender offer by a *Delaware* corporation for stock held by an *Arkansas* resident.

As the Supreme Court recently reiterated in *Ross*, this sort of direct regulation, with *no* corresponding connection to the regulating state is invalid under the dormant Commerce Clause. *See Ross*, 598 U.S. at 376, n.1 (citation omitted). In other words, Illinois cannot project its policy preferences into other states by making itself the arbiter of tender offers occurring in other states that do not and will never have a connection to Illinois. Here, unlike *Edgar*, as discussed in *infra* in section III.C., the Act's enforcement will always have a substantial connection within Minnesota because it only ever applies to Minnesota-licensed manufacturers when their drugs are sold, dispensed, or distributed in Minnesota; the Act can only be enforced against entities that have chosen to have their drugs legally enter the Minnesota marketplace; and the Act does not control the price presented to consumers in other states.

B. *CTS* Controls This Case, Not *Edgar*.

Five years after *Edgar*, a majority of the Supreme Court clarified that the lack of any in-state connection is key to understanding why the Illinois law failed to pass constitutional muster. In *CTS Corp. v. Dynamics Corp. of Am.*, the Court upheld a similar Indiana law limiting out-of-state tender offerors' acquisition of controlling shares in certain corporations. 481 U.S. 69, 93 (1987). Distinguishing *Edgar*, the Court found the Indiana law was limited "only to corporations incorporated in Indiana" with substantial numbers of Indiana shareholders. *Id*. Therefore, "every application of the Indiana Act will affect a substantial number of Indiana residents,

whom Indiana indisputably has an interest in protecting." *Id*. Thus, *Edgar* and *CTS* demonstrate the limited purview of the dormant Commerce Clause's prohibition on non-discriminatory state laws that directly regulate out-of-state commerce: such laws are not forbidden so long as the regulated commerce has a substantial connection to in-state interests.[76]

Minnesota's Act is distinguishable from the Illinois law in *Edgar* in the same way as Indiana's law was distinguished from the Illinois law in *CTS*. The law in *Edgar* was unconstitutionally overbroad because "in some instances [it] regulated extraterritorial transactions for no reason while providing no protection for any legitimate state interest." *Alliant Energy Corp. v. Bie*, 336 F.3d 545, 549 (7th Cir. 2003) (comparing *Edgar* and *CTS*). Like the Indiana law in *CTS*, however, Minnesota's Act will "never affect extraterritorial transactions without providing a corresponding and significant protection for a legitimate interest of local residents." *Id*.

[76] "In practice, states exert regulatory control over each other all the time.... [A] state's geographic territory does not mark the outer limit of its legitimate regulatory concern." G.E. Metzger, *Congress, Article IV, and Interstate Relations*, 120 Harv. L. Rev. 1468, 1521–22 (2007). Indeed, an entire body of conflict of laws cases apply state laws to extraterritorial conduct. *See* K. Florey, *State Courts, State Territory, State Power: Reflections on the Extraterritoriality Principle in Choice of Law and Legislation*, 84 Notre Dame L. Rev. 1057, 1073–74 (2009).

C. The Act does not Restrict Pricing or Set Policy in Other States.

For 60 years, manufacturers seeking access to Minnesota's marketplace must first obtain a license from the Board for this privilege.[77] Minnesota's licensing scheme protects the public by, among other things, ensuring manufacturing facilities have not been shut down by other states[78] and are subject to inspection.[79] Manufacturers agree to follow Minnesota laws, register with the state, and open every manufacturing facility to inspection by Minnesota regulators.[80] Manufacturers knowingly subject themselves to Minnesota's regulatory scheme in exchange for access to Minnesota's market for their drugs. And, because the Act will only ever apply when a Minnesota-licensed manufacturer's generic drug is actually sold, distributed, or dispensed *in Minnesota*; it only regulates Minnesota-bound drugs.

Absent these substantial in-state connections, the Act is completely indifferent to the price out-of-state manufacturers charge to any out-of-state entity. Unlike the law in *Edgar* for example, the Act does not prevent a Wisconsin drug manufacturer from selling excessively priced drugs to an Illinois distributor that sells, distributes, or dispenses them in any other state. The Act does not dictate the terms of such

[77] Minn. Stat. § 151.252(a).
[78] *Id.* at (f).
[79] *Id.* at (h).
[80] Minn. Stat. § 151.252.

wholly out-of-state transactions, Minnesota cannot penalize the parties to it, and therefore Minnesota is not projecting its legislation into these states.

Of course, a manufacturer is not required to make its drugs available in Minnesota at all. If a manufacturer does not obtain a Minnesota license, their drugs cannot be sold, dispensed, or distributed in the state—directly or indirectly, at *any* price.[81] If and when an unlicensed manufacturer's drugs breach Minnesota's territorial borders – whether the manufacturer intended it or not – Minnesota designates these drugs "adulterated,"[82] and subjects them to embargo and condemnation.[83] In this sense, unlicensed out-of-state manufacturers are never regulated directly, but their "adulterated" drugs will be if they arrive in Minnesota. Manufacturers who seek and obtain licensure become subject to laws that affect their out-of-state behavior, but only insofar as such manufacturers' out-of-state behavior is connected to drugs supplied in Minnesota.[84]

---

[81] *Id.* at (a).
[82] Minn. Stat. § 151.35(1).
[83] Minn. Stat. § 151.38.
[84] The district court noted that, at oral argument, the Attorney General conceded that, if the manufacturers did "everything in its power to prevent its drugs from being sold in Minnesota," the Act would still hold a manufacturer liable. App. 578-580; R. Doc. 39, at 30-32. App. 624; R. Doc. 624. The Attorney General did concede at oral argument that a manufacturer could be held liable for acts taken by third party distributors against the terms of a distribution contract signed by the manufacturer, but that is not everything within the manufacturer's power to prevent or avoid violating the Act. The manufacturer could, for example, return their licensure with the state.

A manufacturer thus has a choice: (1) obtain a license to access the Minnesota marketplace and comply with Minnesota's police power regulations over its manufacturing of drugs that are sold, dispensed, or distributed (directly or indirectly) in Minnesota, including the Act, or (2) do not seek out licensure, thereby avoiding Minnesota's regulatory scheme and forgoing the Minnesota market.[85]

Ultimately, when a Minnesota-licensed out-of-state manufacturer excessively increases the price of a generic drug in a sale to an out-of-state distributor, the Act is only triggered when that drug is subsequently sold, dispensed, or delivered to a consumer in Minnesota's territorial borders. Absent this direct and substantial in-state nexus between the out-of-state transaction and Minnesota's police power, the state's cause of action under the Act does not accrue. Therefore, the Act is only ever violated by in-state conduct harming people in Minnesota.

Accordingly, the district court erred as a matter of law when it held that the Act likely applies to wholly out-of-state commerce with *no* connection to Minnesota. Indeed, the opposite is true. The law is constitutional and consistent with the Supreme Court's precedent in *Edgar* and *CTS*.

[85] Minnesota's licensing scheme has stood for decades. AAM has never challenged it and does not do so here. *C.f.*, *Southern Union Co. v. Mo. Pub. Svc. Com'n*, 289 F.3d 503, 507 (8th Cir. 2002) (noting that if the challenged statute was unconstitutional under the dormant Commerce Clause, "it is startling, to say the least, that the statute has gone unchallenged for nearly one hundred years").

D. Because the District Court Misapplied Edgar's Progeny, It Erroneously Found the Act Regulated Commerce with No Connection to Minnesota.

The district court further erred by relying on *Styczynski v. Arnold*, 46 F.4th 907 (8th Cir. 2022) and the Fourth Circuit's assessment of a similar law in *Association for Accessible Medicines v. Frosh*, 887 F.3d 664 (4th Cir. 2018), to strike down Minnesota's Act.

1. The Law in *Styczynski* was Overbroad And Its Plain Language Governed Transactions with No Connection to Minnesota Whatsoever.

In *Styczynski*, this Court struck down a Minnesota law that sought to regulate physically-out-of-state bullion transactions between a company with no Minnesota connection (or license) and a Minnesota resident who was not, at the time of the transaction, in Minnesota. 46 F.4th at 913. None of the regulated entities needed to have any presence in or connection to Minnesota to trigger the law. The law could have applied to a trader in Nevada who had the misfortune to make a bullion transaction with a vacationing Minnesotan after a lucky night at a Las Vegas craps table. Like the law struck down in *Edgar*, the bullion law could apply to wholly out-of-state transactions with no substantial nexus to the regulating state's interests. Mere Minnesota citizenship of one party to the transaction was insufficient.

Unlike the law in *Styczynski*, the Act will only ever apply to conduct that occurs in Minnesota by actors who seek out and maintain a presence in the state.

Each party to the out-of-state generic drug transaction is voluntarily licensed in Minnesota to manufacture, sell, and distribute prescription drugs into Minnesota and the Act's excessive price prohibition does not attach until a drug is actually sold, distributed, or dispensed *in Minnesota*. The district court erred in concluding that *Styczynski* supports the injunction.

2. The Maryland Act Struck Down In Frosh Was Overbroad.

The district court also relied on *Association for Accessible Medicines v. Frosh*, where AAM made a similar dormant Commerce Clause challenge to a Maryland price-gouging ban on generic drugs. 887 F.3d 664. Maryland's law prohibited drug manufacturers from charging unconscionable prices on drugs "made available for sale in Maryland." *Id.* at 666. As written, the Maryland law conceivably applied to transactions of drugs consummated entirely out-of-state, so long as the drugs were separately "made available for sale in Maryland." *Id.* at 673. The Maryland law was triggered regardless of whether any pill from an out-of-state sale ever actually made it into Maryland. *Id*. at 666.

Minnesota's Act is also distinguishable from the Maryland law in *Frosh* in the same way Indiana's law in *CTS* was distinguished from the Illinois law in *Edgar*. The laws in *Frosh* and *Edgar* "in some instances regulated extraterritorial transactions for no reason while providing no protection for any legitimate state interest." *Bie*, 336 F.3d at 549. The Minnesota Act and the law in *CTS*, in contrast,

"never affect extraterritorial transactions without providing a corresponding and significant protection for a legitimate interest of local residents." *Id*. Here, the Minnesota Legislature adopted the Act after many years of study into the problem of generic drug price-gouging and its harmful effects on consumers in Minnesota who have no meaningful choice about whether to purchase drugs at excessive prices. Minnesota's response to this problem falls squarely within the heartland of state police power regulations for the health and safety of its citizens.

Ultimately, unlike the Illinois law in *Edgar*, the bullion law in *Styczynski*, or the Maryland law in *Frosh*, there is no plausible interpretation of the Act that would result in an out-of-state manufacturer violating the Act because of a purely out-of-state sale, distribution, or dispensing of a drug in another state. Like the Indiana law in *CTS*, the Act is constitutional precisely because it only regulates out-of-state sales once a substantial in-state nexus is established.

3. Manufacturers' Distribution Choices Are Not Constitutionally Protected.

The district court granted undue credence to AAM's claim that its members might lack knowledge that their drugs would subsequently wind up in Minnesota, or lack the ability to control where their drugs are distributed. Faced with these barriers, the district court credited AAM's claim that its manufacturers confronted an impossible choice to violate the Act or pay a hefty penalty to leave the state because of it.

But AAM's claim that they lack control of their drugs once they leave their custody is not a problem with constitutional significance. The dormant Commerce Clause "protects the interstate market, not particular firms, from prohibitive or burdensome regulations." *Exxon Corp. v. Gov. of Maryland*, 437 U.S. 117, 127-28 (1978). It does not protect firms' chosen "methods of operation." *Id.* at 127. AAM never claims its members are *actually incapable* of segregating their products for state marketplaces.

Dormant Commerce Clause challenges to the direct regulation of out-of-state entities regularly fail when regulated entities have the ability to segregate products bound for the regulating state. Even if the cost of compliance might be high, the burden of compliance is "not a sufficient basis on which to establish a dormant Commerce Claim where the state law at issue does not otherwise interfere with interstate commerce." *SPGGC, LLC v. Blumenthal*, 505 F.3d 183, 196 (2d Cir. 2007). When a manufacturer is "unwilling to modify their production and distribution systems to differentiate between" products bound for specific states, "[s]uch a burden is simply attributable to legitimate intrastate regulation" and "manufacturers are not required to adhere to the [state] rule in other states." *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 110-11 (2d Cir. 2001). Courts do not

consider the costs of compliance in shifting distribution channels or manners of doing business in dormant Commerce Clause challenges.[86]

To be sure, the Act may affect whether and how out-of-state manufacturers choose to do business in the Minnesota marketplace. An out-of-state manufacturer accessing Minnesota's market might need to alter its business practices, contracts with distributors, or segregate products destined for Minnesota to avoid incurring liability under the Act. But these are not cognizable Commerce Clause concerns. Indeed, the district court's emphasis on a manufacturers single price-setting decision as the regulated "transaction" is improperly narrow, ignoring the multitude of other characteristics throughout the supply chain that states can simultaneously regulate under the Commerce Clause. *See Swanson v. Integrity Advance*, LLC, 870 N.W.2d 90, 94-96 (Minn. 2015) (Stras, J.) (rejecting 'unjustifiably narrow' definition of commerce that fails to include entire transaction of 'production, distribution, and consumption of commodities'). Accordingly, the district court erred in crediting

[86] *See also Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070, 1102–03 (9th Cir. 2013) (upholding a statute against a dormant Commerce Clause challenge where non-compliant and compliant ethanol was mixed prior to distribution); *Int'l Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 646–47 (6th Cir. 2010) (same, for dairy products); *Hampton Feedlot, Inc. v. Nixon*, 249 F.3d 814, 819 (8th Cir. 2001) (livestock); *Cotto Waxo, Co. v. Williams,* 46 F.3d 790, 793 (8th Cir. 1995) (petroleum-based sweeping compounds); *TitleMax of Delaware, Inc. v. Weissmann*, 24 F.4th 230, 238-239 (3d Cir. 2022) (collection statute applying extraterritorially when collateral is a Pennsylvania-registered vehicles); *Swanson,* 870 N.W.2d at 95 (payday loans).

AAM's arguments about unknown third-party distribution, and erred in failing to consider that AAM's members could simply distribute their pharmaceuticals directly into Minnesota.

By considering these constitutionally-insignificant factors, the district court misapplied the law and ignored a sophisticated and voluntary licensing regime intimately regulating any business manufacturers choose to conduct in Minnesota. In doing so, the district court erroneously enjoined a non-discriminatory and presumptively constitutional act of the Minnesota Legislature.

IV. THE OTHER *DATAPHASE* FACTORS WEIGH IN FAVOR OF THE STATE.

In reviewing the motion for a preliminary injunction and applying *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 114 (8th Cir. 1981), the district court erroneously found that the factors of "public interest" and "balance of the harms" were "a wash."[87]

The district court's sole support for AAM's position under the "public interest" factor relies entirely on whether the Act is constitutional. The district court found that it is "in the public interest to protect constitutional rights," citing *Carson v. Simon*, 978 F.3d 1051, 1061 (8th Cir. 2020).[88] To be clear, *Carson* and the cases it cites evince a concern of jealously guarding First Amendment rights, not the

[87] App. 19-21; R. Doc. 1, at 17-19.
[88] *Id.*

unprotected economic interests of continuing to utilize voluntary distribution systems AAM has argued for here. But, moreover, this support evaporates if AAM is unlikely to succeed on the merits of their claim, as the Attorney General describes, *supra*.

The district court also held that the "balance of the harms" was a wash because AAM's members' financial harms were "unclear" and Minnesotans' health impacts were "not well developed."[89] But "the public interest . . . is served by maintaining the ability to enforce [a] law adopted by the Minnesota Legislature." *Carson v. Simon*, 978 F.3d 1051, 1061 (8th Cir. 2020). Moreover, courts have repeatedly found that, when a law's putative benefits include providing access to "prescription drugs to [State] citizens who could not otherwise afford them," the local benefits are "substantial." *See, e.g.*, *Pharm. Res. and Mfrs. of Amer. v. Concannon*, 249 F.3d 66, 84 (1st Cir. 2001) (citations omitted). It follows that preliminarily enjoining a law that provides "substantial" benefits is a substantial harm that cannot be outweighed by the choices of two manufacturers to allegedly abstain from price increases.

Because the *Dataphase* factors weigh heavily in favor of the State, the district court's injunction should be reversed.

---

[89] *Id.*

CONCLUSION

The district court erred as a matter of law when it held that the Act likely violates the dormant Commerce Clause. Because the Act only ever applies to Minnesota-licensed manufacturers when their drugs are actually sold, distributed, or dispensed in Minnesota, it only regulates out-of-state transactions with a substantial nexus in Minnesota. Because the district court erred as a matter of law, it was an abuse of discretion to enter a preliminary injunction. This Court should reverse the district court, vacate the injunction, and remand for further proceedings.

Dated: February 22, 2024

Respectfully submitted,

KEITH ELLISON
Attorney General
State of Minnesota

/s/ Nick Pladson
NICK PLADSON
Assistant Attorney General
Atty. Reg. No. 0388148

445 Minnesota Street, Suite 1400
St. Paul, Minnesota 55101-2131
(651) 300-7083 (Voice)
(651) 296-7438 (Fax)
Nick.Pladson@ag.state.mn.us

ATTORNEY FOR APPELLANT

CERTIFICATE OF COMPLIANCE
WITH FRAP 32

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 8,148 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 365 in 14 pt Times New Roman font.

/s/ Nick Pladson
NICK PLADSON
Assistant Attorney General

CERTIFICATE OF COMPLIANCE
WITH 8th Cir. R. 28A(h)(2)

The undersigned, on behalf of the party filing and serving this brief and addendum, certifies that the brief and addendum have been scanned for viruses and that they are virus-free.

/s/ Cole M. Werner
COLE M. WERNER